

Bausch & Lomb BPZ02 MultiPurpose Solution**1. Submitter Information**

Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609

Contact Person

Glenn A. Davies, O.D.
Director Global Regulatory Affairs

NOV 18 2009

Telephone Number

(585) 338-8215

2. Device Name

Common Name: Soft (hydrophilic) Contact Lens Care Solution

Trade Name: BPZ02 MultiPurpose Solution

Classification: Accessories, Solution, Ultrasonic Cleaners for Lenses

Device classification: Class II (21 CFR §886.5928)

Product Code: LYL

3. Predicate Devices

CIBA Vision AQuify Multi-Purpose Solution (K033608)

Alcon OPTI-FREE® RepleniSH® Multi-Purpose Disinfecting Solution (K050729)

4. Description of the Device

Bausch & Lomb BPZ02 MultiPurpose Solution is a sterile, isotonic solution that contains hyaluronan, sulfobetaine, poloxamine 1107, boric acid, sodium borate, edetate disodium and sodium chloride; and preserved with a dual disinfection system. The sterile solution is packaged in a plastic bottle with a tamper evident seal and labeled with a lot number and expiration date.

5. Intended Use

Bausch & Lomb® BPZ02 MultiPurpose Solution is indicated for use in the daily conditioning, cleaning, removal of protein deposits, rinsing, chemical (not heat) disinfection, and storage of soft (hydrophilic) contact lenses, including silicone hydrogel contact lenses, as recommended by your eye care practitioner.

6. Description of Safety and Substantial Equivalence

A series of preclinical and clinical testing was performed to demonstrate the safety and effectiveness of Bausch & Lomb BPZ02 MultiPurpose Solution. A summary of the test results is provided below:

Biocompatibility

Cytotoxicity, ocular irritation, oral toxicity, sensitization and *in vivo* ocular biocompatibility studies were completed for Bausch & Lomb BPZ02 MultiPurpose Solution. The test results demonstrated that BPZ02 MultiPurpose Solution is non-cytotoxic, and not an ocular irritant or sensitizing agent.

Microbiology

The sponsor conducted a series of studies according to EN ISO 14729:2001 *Ophthalmic optics – Contact lens care products – Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses* and EN ISO 14730:2000 *Ophthalmic optics – Contact lens care products – Antimicrobial preservative efficacy testing and guidance on determining discard date* and demonstrate Bausch & Lomb BPZ02 MultiPurpose Solution exceeds the criteria for disinfection and preservative efficacy.

Lens Compatibility

The results of lens compatibility studies demonstrate Bausch & Lomb BPZ02 MultiPurpose Solution is compatible with soft contact lenses including silicone hydrogel contact lenses.

Cleaning Efficacy

The cleaning efficacy of the solution was evaluated through the determination of the Critical Micelle Concentration. The surfactant concentrations are well above the CMC for the individual surfactants.

Clinical Study

Bausch & Lomb conducted a controlled clinical study with soft (hydrophilic) contact lenses, including silicone hydrogel lenses, comparing the safety and efficacy of Bausch & Lomb BPZ02 MultiPurpose Solution to AQuify Multi-Purpose Disinfecting Solution. The results of the study support a substantial equivalence determination.

7. Substantial Equivalence

The cumulative results of laboratory, *in vitro*, *in vivo*, and clinical testing sponsored by Bausch & Lomb demonstrate that the safety, efficacy and performance of Bausch & Lomb BPZ02 MultiPurpose Solution are substantially equivalent to AQuify Multi-Purpose Solution and OPTI-FREE Express Multi-Purpose Disinfecting Solution for soft contact lenses, including silicone hydrogel contact lenses.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Bausch & Lomb
c/o Glenn A. Davies, O.D.
Director, Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14609

NOV 18 2009

Re: K083757

Trade/Device Name: Bausch & Lomb® BPZ02 MultiPurpose Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: II
Product Code: LYL
Dated: November 10, 2009
Received: November 12, 2009

Dear Dr. Davies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083757

Device Name: Bausch & Lomb® BPZ02 MultiPurpose Solution

Indications for Use:

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Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter-Use X
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

C G1
(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K083757